

CLAIMS

1. A composition for the treatment of post-surgical articular or incisional pain or discomfort consisting essentially of an aqueous dispersion of insoluble non-crosslinked type I fibrillar atelopeptide collagen and a pharmaceutical agent selected from the group consisting of anesthetics, analgesics, antibiotics, sedatives, opioids and antitumor agents; wherein the composition is formulated to release an effective amount of the pharmaceutical agent from the collagen for at least 48 hours.

2. The composition of claim 1, wherein the pharmaceutical agent is soluble.

3. The composition of claim 1, wherein the composition is formulated to release an effective amount of the pharmaceutical agent from the collagen for at least 72 hours.

4. The composition of claim 1, wherein the ratio of collagen to pharmaceutical agent is from about 0.5:1 to about 50:1.

5. The composition of claim 4, wherein the ratio of collagen to pharmaceutical agent is about 1:1.

6. The composition of claim 1, wherein the collagen consists essentially of at least 95% Type I non-crosslinked fibrillar atelopeptide collagen.

7. The composition of claim 1, wherein the collagen contains 5% or less of Type III collagen.

8. The composition of claim 1, wherein the pharmaceutical agent is an anesthetic.

9. The composition of claim 8, wherein the anesthetic is bupivacaine, lidocaine, procaine, procainamide, tetracaine, mepivacaine, or etidocaine.

10. The composition of claim 1, wherein the collagen is human collagen or bovine dermal collagen.

11. The composition of claim 1, wherein the pharmaceutical agent is an opioid.

12. The composition of claim 11, wherein the opioid is morphine, codeine, demerol, or methadone.

13. The composition of claim 1, wherein the pharmaceutical agent is a sedative.

14. The composition of claim 13, wherein the sedative is diazepam or flurazepam.

15. The composition of claim 1, wherein the pharmaceutical agent is an antitumor agent.

16. The composition of claim 15, wherein the antitumor agent is methotrexate or tamoxifen.

17. The composition of claim 1, wherein the pharmaceutical agent is an antibiotic.

18. The composition of claim 1, wherein the concentration of collagen is from about 3 mg/ml to about 100 mg/ml.

19. The composition of claim 18, wherein the concentration of collagen is about 65 mg/ml.

20. The composition of claim 18, wherein the concentration of collagen is from about 16 mg/ml to about 28 mg/ml.

21. The composition of claim 1, wherein the concentration of pharmaceutical agent is about 4-30 mg/ml.

22. The composition of claim 21, wherein the concentration of pharmaceutical agent is from about 4 mg/ml to about 10 mg/ml

23. The composition of claim 1, wherein the total amount of pharmaceutical agent released is from about 5 mg to 1g.

24. The composition of claim 1, wherein the amount of pharmaceutical agent released is from about 2-15 mg per day.

25. The composition of claim 24, wherein the amount of pharmaceutical agent released is about 10 mg per day.

26. The composition of any of claims 1, further including one or more pharmaceutically acceptable excipient(s).

27. A composition for the treatment of post-surgical articular or incisional pain or discomfort consisting essentially of an aqueous dispersion of insoluble non-crosslinked type I fibrillar atelopeptide collagen and bupivacaine;

wherein the composition is formulated to release an effective amount of bupivacaine from the collagen for at least 48 hours.

28. The composition of claim 27, wherein the bupivacaine is soluble.

29. The composition of claim 27, wherein the composition is formulated to release an effective amount of bupivacaine from the collagen for at least 72 hours.

30. The composition of claim 27, wherein the ratio of collagen to bupivacaine is from about 0.5:1 to about 50:1.

31. The composition of claim 30, wherein the ratio of collagen to bupivacaine is from about 1:1 to about 5:1

32. The composition of claim 27, wherein the collagen consists essentially of at least 95% Type I non-crosslinked fibrillar atelopeptide collagen.

33. The composition of claim 27, wherein the collagen contains 5% or less of Type III collagen.

34. The composition of claim 27, wherein the concentration of collagen is from about 10 mg/ml to about 100 mg/ml.

35. The composition of claim 34, wherein the concentration of collagen is about 65 mg/ml.

36. The composition of claim 34, wherein the concentration of collagen is from about 16 mg/ml to about 28 mg/ml.

37. The composition of claim 27, wherein the concentration of bupivacaine is about 4-30 mg/ml.

38. The composition of claim 37, wherein the concentration of bupivacaine is from about 4 mg/ml to about 10 mg/ml

39. The composition of claim 27, wherein the total amount of bupivacaine released is from 5 mg to 1g.

40. The composition of claim 27, wherein the amount of bupivacaine released is about 2-15 mg per day.

41. The composition of claim 27, further including one or more pharmaceutically acceptable excipients.

42. A method for the treatment of post-surgical pain or discomfort in a joint(s) comprising the step of

intra-articularly administering to a joint(s) in a patient a composition consisting essentially of an aqueous dispersion of insoluble non-crosslinked Type I fibrillar atelopeptide collagen and a pharmaceutical agent selected from the group consisting of anesthetics, analgesics, antibiotics, sedatives, opioids and antitumor agents, wherein the composition is formulated to release an effective amount of the pharmaceutical agent from the collagen for at least 48 hours, and wherein the composition is administered before, during or after a surgical procedure.

43. The method of claim 42, wherein the joint is a knee, shoulder, ankle, hip, wrist, elbow or temporomandibular joint.

44. The method of claim 43, wherein the joint is a knee.

45. The method of claim 42, wherein the patient is a human or veterinary patient.

46. The method of claim 45, wherein the patient is a human.

47. The method of claim 42, wherein the composition is administered before the surgical procedure.

48. The method of claim 47, wherein the method further comprises the step of at least one additional administration of the composition during or after the surgical procedure.

49. The method of claim 42, wherein the composition is administered during the surgical procedure.

50. The method of claim 42, wherein the composition is administered after the surgical procedure.

51. The method of claim 42, wherein the composition is administered via a catheter.

52. The method of claim 42, wherein the surgical procedure is arthroscopy, arthrotomy, implantation of chondrocytes, implantation of cartilage, partial joint arthroplasty or total joint arthroplasty

53. The method of claim 42, wherein the surgical procedure is used in the treatment of a condition selected from the group consisting of meniscal injury, anterior cruciate ligament injury, rotator cuff injury, carpal tunnel syndrome, synovitis, chondromalacia, patellar tendon rupture, tibial tubercle fracture, loose bodies of bone or cartilage, osteochondritis dissecans, adhesive capsulitis,

impingement syndrome, shoulder dislocation, Dupuytren's syndrome, scaphoid fracture, stenosing tenosynovitis, lateral facet syndrome, anterior patello-femoral pain syndrome, lateral pressure syndrome, malalignment syndrome, and maltracking syndrome.

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54. The method of claim 42, wherein the condition is not a degenerative articular process.

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55. The method of claim 42, wherein the composition is formulated to release an effective amount of the pharmaceutical agent from the collagen for at least 72 hours.

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56. The method of claim 42, wherein the ratio of collagen to pharmaceutical agent is from about 0.5:1 to about 50:1.

57. The method of claim 42, wherein the collagen consists essentially of at least 95% Type I non-crosslinked fibrillar atelopeptide collagen.

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58. The method of claim 42, wherein the collagen contains 5% or less of Type III collagen.

59. The method of claim 42, wherein the pharmaceutical agent is an anesthetic.

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60. The method of claim 59, wherein the anesthetic is bupivacaine, lidocaine, procaine, procainamide, tetracaine, mepivacaine, or etidocaine.

61. The method of claim 42, wherein the collagen is human collagen or bovine dermal collagen.

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62. The method of claim 42, wherein the pharmaceutical agent is an opioid.

63. The method of claim 62, wherein the opioid is morphine, codeine, demerol, or methadone.

64. The method of claim 42, wherein the pharmaceutical agent is a sedative.

65. The method of claim 64, wherein the sedative is diazepam or flurazepam.

66. The method of claim 42, wherein the pharmaceutical agent is an antitumor agent.

67. The method of claim 66, wherein the antitumor agent is methotrexate or tamoxifen.

68. The method of claim 42, wherein the concentration of collagen is from about 3 mg/ml to about 100 mg/ml.

69. The method of claim 42, wherein the concentration of pharmaceutical agent is about 4-30 mg/ml.

70. The method of claim 69, wherein the concentration of pharmaceutical agent is from about 4 mg/ml to about 10 mg/ml

71. The method of claim 42, wherein the total amount of pharmaceutical agent released is from about 5 mg to 1 g.

72. The method of claim 42, wherein the amount of pharmaceutical agent released is from about 2-15 mg per day.

73. The method of claim 72, wherein the amount of pharmaceutical agent released is about 10 mg per day.

74. The method of claim 42, wherein the amount of composition administered is greater than 2 mL.

75. The method of claim 42, wherein the composition further includes one or more pharmaceutically acceptable excipient(s).

76. A method for the treatment of post-surgical pain or discomfort associated with one or more incisions comprising the step of administering to a patient's incision(s) a composition consisting essentially of an aqueous dispersion of insoluble non-crosslinked type I fibrillar atelopeptide collagen and a pharmaceutical agent selected from the group consisting of anesthetics, analgesics, antibiotics, sedatives, opioids and antitumor agents, wherein the composition is formulated to release an effective amount of the pharmaceutical agent from the collagen for at least 48 hours, and wherein the composition is administered before, during or after a surgical procedure.

77. The method of claim 76, wherein the surgical procedure is an abdominal, spinal or breast operation.

78. The method of claim 77, wherein the abdominal operation is a cesarean birth, hernia repair, or hysterectomy.

79. The method of claim 76, wherein the composition is administered via injection.

80. The method of claim 76, wherein the patient is a human or veterinary patient.

5 81. The method of claim 80, wherein the patient is a human.

82. The method of claim 76, wherein the composition is administered before the surgical procedure.

10 83. The method of claim 82, wherein the method further comprises the step of at least one additional administration of the composition during or after the surgical procedure.

15 84. The method of claim 76, wherein the composition is administered during the surgical procedure.

85. The method of claim 76, wherein the composition is administered after the surgical procedure.

20 86. The method of claim 76, wherein the composition is administered via a catheter.

87. The method of claim 76, wherein the pharmaceutical agent is an anesthetic.

25 88. The method of claim 87, wherein the anesthetic is bupivacaine.

89. A method for the treatment of post-surgical pain or discomfort in a joint(s) comprising the step of

intra-articularly administering to a joint(s) in a patient a composition consisting essentially of an aqueous dispersion of insoluble non-crosslinked Type I fibrillar atelopeptide collagen and bupivacaine, wherein the composition is formulated to release an effective amount of bupivacaine from the collagen for at least 48 hours, and wherein the composition is administered before, during or after a surgical procedure.

90. The method of claim 89, wherein the joint is a knee, shoulder, ankle, hip, wrist, elbow or temporomandibular joint.

91. The method of claim 90, wherein the joint is a knee.

92. The method of claim 89, wherein the patient is a human or veterinary patient.

93. The method of claim 92, wherein the patient is a human.

94. The method of claim 89, wherein the composition is administered before the surgical procedure.

95. The method of claim 94, wherein the method further comprises the step of at least one additional administration of the composition during or after the surgical procedure.

96. The method of claim 89, wherein the composition is administered during the surgical procedure.

97. The method of claim 89, wherein the composition is administered after the surgical procedure.

98. The method of claim 89, wherein the composition is administered via a catheter.

99. The method of claim 89, wherein the surgical procedure is arthroscopy, arthrotomy, implantation of chondrocytes, implantation of cartilage, partial joint arthroplasty or total joint arthroplasty

100. The method of claim 89, wherein the surgical procedure is used in the treatment of a condition selected from the group consisting of meniscal injury, anterior cruciate ligament injury, rotator cuff injury, carpal tunnel syndrome, synovitis, chondromalacia, patellar tendon rupture, tibial tubercle fracture, loose bodies of bone or cartilage, osteochondritis dissecans, adhesive capsulitis, impingement syndrome, shoulder dislocation, Dupuytren's syndrome, scaphoid fracture, stenosing tenosynovitis, lateral facet syndrome, anterior patello-femoral pain syndrome, lateral pressure syndrome, malalignment syndrome, and maltracking syndrome.

101. The method of claim 89, wherein the composition is formulated to release an effective amount of bupivacaine from the collagen for at least 72 hours.

102. The method of claim 89, wherein the ratio of collagen to bupivacaine is from about 0.5:1 to about 50:1.

103. The method of claim 89, wherein the collagen consists essentially of at least 95% Type I non-crosslinked fibrillar atelopeptide collagen.

104. The method of claim 89, wherein the collagen contains 5% or less of Type III collagen.

105. The method of claim 89, wherein the collagen is human collagen or bovine dermal collagen.

106. The method of claim 89, wherein the concentration of collagen is from about 3 mg/ml to about 100 mg/ml.

107. The method of claim 89, wherein the concentration of bupivacaine is about 4-30 mg/ml.

108. The method of claim 107, wherein the concentration of bupivacaine is from about 4 mg/ml to about 10 mg/ml

109. The method of claim 89, wherein the total amount of bupivacaine released is from about 5 mg to 1g.

110. The method of claim 89, wherein the amount of bupivacaine released is from about 2-15 mg per day.

111. The method of claim 110, wherein the amount of bupivacaine released is about 10 mg per day.

112. The method of claim 89, wherein the amount of composition administered is greater than 2 mL.

113. The method of claim 89, wherein the composition further includes one or more pharmaceutically acceptable excipient(s).

114. A catheter for use in the treatment of articular injury, the catheter comprising a lumen and being adapted for use in arthroscopy or arthrotomy, wherein the catheter comprises in its lumen a composition of claim 1.